

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING

To:

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## PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing  
(day/month/year) 06 MAY 2004 (06.05.2004)

Applicant's or agent's file reference  
OF03P067

**REPLY DUE** within 2 months from  
the above date of mailing

International application No.

**PCT/KR2003/000882**

International filing date (day/month/year)

01 MAY 2003 (01.05.2003)

Priority date(day/month/year)

02 MAY 2002 (02.05.2002)

International Patent Classification (IPC) or both national classification and IPC

**IPC7 A61K 31/133**

Applicant

DOOSAN CORPORATION et al

1. This written opinion is the first (first,etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When ? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d)

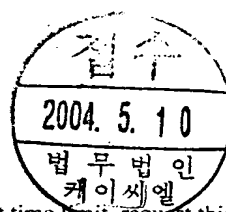
How ? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3  
For the form and the language of the amendments, see Rules 66.8 and 66.9

Also For an additional opportunity to submit amendments, see Rule 66.4  
For an examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis  
For an informal communication with the examiner, see Rule 66.6


If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary

examination report must be established according to Rule 69.2 is: 23 AUGUST 2004 (23.08.2004)



Name and mailing address of the IPEA/KR

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# WRITTEN OPINION

International application No.

PCT/KR2003/000882

## I. Basis of the opinion

### 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement) under Article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language English which is

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☒ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheet/fig \_\_\_\_\_

### 5.

- ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-13 (Yes)
	Claims	None (No)
Inventive step (IS)	Claims	6-8 (Yes)
	Claims	1-5, 9-13 (No)
Industrial applicability (IA)	Claims	1-13 (Yes)
	Claims	None (No)

**2. Citations and explanations****(1) Claims 1-5, 10-11**

본원발명의 특허청구범위 제1항 내지 제5항 및 제10항 내지 제11항은 N,N-디메틸피토스핑고신을 유효성분으로 함유한 항암제조성물, 이를 포함하는 암 치료용 키트 및 과증식성 질환 치료용 조성물에 관한 발명이나 본원발명의 우선권 주장일 전에 공개된 FEBS Letters, 499(1/2), 82-86, 2001(이하 D1이라함)에 피토스핑고신, N-아세틸피토스핑고신 등이 강력한 세포독성이 있음이 기재되어 있는 바, 양자를 비교해보면, 피토스핑고신 골격의 화합물이 세포독성을 가진다는 점에서 동일하고 다만, 본원발명의 N,N-디메틸피토스핑고신이 D1에 기재되어 있지는 않지만 피토스핑고신의 골격에 N,N-디메틸과 같은 구조변경은 당업자가 당연히 선택할 수 있는 정도에 지나지 않고 이로 인한 현저한 효과(즉, N,N-디메틸피토스핑고신이 피토스핑고신이나 N-아세틸피토스핑고신에 비해 현저한 효과가 있음)가 있다고 볼 수도 없습니다. 따라서 상기 청구항들은 D1으로부터 자명한 것으로 진보성이 없습니다.

**(2) Claims 9, 12**

본원발명의 특허청구범위 제9, 12항은 N,N-디메틸피토스핑고신을 함유한 항염제조성물 및 항균제조성물에 관한 발명이나 본원발명의 우선권 주장일 전에 공개된 WO 00/53568호(2000.9.14.; 이하 D2라함)에 피토스핑고신의 유기산 염을 함유한 항염제, 항균제조성물이 기재되어 있어 양자를 비교해보면, 피토스핑고신골격의 화합물을 포함하는 항염제, 항균제조성물이라는 점에서 양자 동일합니다. 다만, 본원발명은 N,N-디메틸피토스핑고신이고 D2에는 피토스핑고신의 유기산 염이라는 점에서 미차가 있으나 피토스핑고신에 N,N-디메틸화와 같은 구조적 변경을 하는 것은 (1)에서도 기재되어 있듯이 단순한 구조적 변경에 불과하며 이로 인한 현저한 효과가 있다고 볼 수도 없으므로 상기 청구항은 D2로부터 자명한 것으로 진보성이 없습니다.

**(3) Claims 13**

본원발명의 특허청구범위 제13항은 피토스핑고신을 환원제와 포름알데히드와 반응시켜 N,N-디메틸피토스핑고신을 제조하는 방법에 관한 것이나 이러한 amine의 reductive methylation은 "Advanced Organic Chemistry, 4th edition, Wiley-Interscience Publication, Jerry March, 1992, pp.898-901(이하 D3이라함)에도 기재되어 있듯이 이미 공지된 기술에 불과합니다. 따라서 이러한 제조방법을 피토스핑고신에 적용하여 N,N-디메틸피토스핑고신을 제조하는 것은 당업자에게 자명한 것이므로 상기 청구항은 진보성이 없습니다.